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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,042	07/25/2003	Michael Marquant	21084 US/pd-d	4047
23690	7590	09/10/2009		
ROCHE DIAGNOSTICS OPERATIONS INC. 9115 Hague Road Indianapolis, IN 46250-0457			EXAMINER HYUN, PAUL SANG HWA	
			ART UNIT 1797	PAPER NUMBER
			NOTIFICATION DATE 09/10/2009	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/628,042	<b>Applicant(s)</b> MARQUANT ET AL.	
	<b>Examiner</b> PAUL S. HYUN	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6-8 and 11-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6-8 and 11-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/26/09</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The after-final amendment filed by Applicant on August 26, 2009 has been acknowledged. Applicant cancelled claims 24-28. Claims 1, 2, 4, 6-8 and 11-22 remain pending.

The IDS filed by Applicant on August 26, 2009 has been acknowledged.

Although claims 1, 2, 4, 6-8 and 11-22 were allowed in the previous Office action, new grounds of rejection are hereby made in light of the Husar reference cited in the IDS filed by Applicant.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **1, 2, 6, and 15-17 and 19-22** are rejected under 35 U.S.C. 102(b) as being anticipated by Husar (US 2002/0061260 A1).

Husar discloses a device for analyzing liquid samples (see Fig. 2). The device comprises layers (i.e. transport layer 2 and support layer 3) that are sandwiched together to define a plurality of channels and chambers therebetween (see Fig. 14) wherein one channel 5 functions as an inlet and chamber 8 functions as a measuring site. The side of the support layer 3 that faces the transport layer 2 is coated with an electrode layer 17 (see claim 24) comprising a pair of electrodes for electrophoretically

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separating constituents of the liquid sample wherein one electrode can be made from gold (see [0125]). The device can further comprise optical windows (see [0081]). In one embodiment, Husar discloses a device comprising a plurality of devices stacked together using an adhesive (see [0097]) in a staggered arrangement such that the electrode layer 17 extends beyond an adjacent transport layer 2 (see Fig. 7). Each device can accommodate a unique reagent for measuring a different parameter of the sample liquid (see [0196]).

With respects to claim 19, it should be noted that the claimed control site is limited by the recitation of the intended use of the control site rather than what the control site actually comprises. The limitation “for checking the filling... control site” do not further limit the structure of the control site.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims **4 and 11-13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Husar in view of Oloman et al. (US 4,118,305).

Husar does not disclose an insulating foil mask in the transport layer.

Oloman et al. disclose a device for conducting reactions wherein the device comprises a pair of electrodes and a porous, hydrophilic insulating material separating the two electrodes (see claim 1). The porous insulating material permits free flow of liquid between the electrodes while providing electrical insulation between the electrodes. In light of the disclosure of Oloman et al., it would have been obvious to one

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of ordinary skill in the art to provide a hydrophilic, porous insulating layer between the electrodes of the microfluidic device disclosed by Husar so that flow of liquid between the electrodes is permitted while providing electrical insulation between the electrodes.

Claims **7 and 8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Husar in view of Chan (US 5,565,143).

Husar does not disclose the use of an electrode made from Ag/AgCl mixture.

Chan discloses that it is well known in the art to use Ag/AgCl as an electrode in electrophoretic separation applications because the electrode allows the delivery of continuous current at a low and steady voltage (see lines 15-25, col. 1). In light of the disclosure of Chan, it would have been obvious to one of ordinary skill in the art to use Ag/AgCl mixture as one of the electrodes in the device disclosed by Husar.

Claim **14** is rejected under 35 U.S.C. 103(a) as being unpatentable over Husar in view of Stapleton et al. (US 5,922,604).

Although Husar discloses that the device can be pre-packaged with reagents, Husar does not disclose the use of dry reagents.

Stapleton et al. disclose a microfluidic device comprising reagents immobilized to the surface of the microfluidic channels wherein the reagents are dry (see lines 40-50, col. 11). In light of the disclosure of Stapleton et al., it would have been obvious to one of ordinary skill in the art to provide dried reagents to the device disclosed by Husar since dry reagents have longer shelf lives.

Claim **18** is rejected under 35 U.S.C. 103(a) as being unpatentable over Husar in view of Weigl et al. (US 2001/0027745 A1).

Husar does not disclose a vent.

Weigl et al. disclose a microfluidic device comprising vents (see [0100]). The vents facilitate directional flow of fluids inside microfluidic devices by venting trapped air. In light of the disclosure of Weigl et al., it would have been obvious to one of ordinary skill in the art to provide vents to the device disclosed by Husar to facilitate that fluid flow.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL S. HYUN whose telephone number is (571)272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul S Hyun/  
Examiner, Art Unit 1797

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797